

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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- 1	APPLICATION NO. FILING DATE FIRST		ST NAMED IN	MED INVENTOR		ATTORNEY DOCKET NO.	
•	087900,220	07/24/97	MIAO			N	ONV044.01
ſ	FOLEY HOAG	PATENT GROUP FOLEY HOAG AND ELIOT		1925	ا ٦	EXAMINER WESSENDORF.T	
		FICE SQUARE				ART UNIT	PAPER NUMBER
	BOSTON MA (2109			_	1648	7
					C	ATE MAILED:	09/25/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 2 08/900,200 Applicant(s)

Miao et al

Examiner

T. Wessendorf

Group Art Unit 1648

Responsive to communication(s) filed on Aug 24, 1998							
This action is FINAL .							
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.							
A shortened statutory period for response to this action is set to e is longer, from the mailing date of this communication. Failure to application to become abandoned. (35 U.S.C. § 133). Extension 37 CFR 1.136(a).	respond within the period for response will cause the						
Disposition of Claims							
	is/are pending in the application.						
Of the above, claim(s)							
Claim(s)							
☐ Claim(s)							
Claim(s)							
☑ Claims 1-48							
Application Papers ☐ See the attached Notice of Draftsperson's Patent Drawing I	Pavious PTO-948						
The drawing(s) filed on is/are objected							
☐ The proposed drawing correction, filed on	is _approved _disapproved.						
☐ The specification is objected to by the Examiner.							
☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. § 119							
oxed Acknowledgement is made of a claim for foreign priority un	nder 35 U.S.C. § 119(a)-(d).						
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been							
☐ received.							
☐ received in Application No. (Series Code/Serial Numb	per)						
received in this national stage application from the International Bureau (PCT Rule 17.2(a)).							
*Certified copies not received:	*Certified copies not received:						
☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).							
Attachment(s)							
☐ Notice of References Cited, PTO-892							
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s	s)						
☐ Interview Summary, PTO-413							
\square Notice of Draftsperson's Patent Drawing Review, PTO-948							
☐ Notice of Informal Patent Application, PTO-152							
Other:							
Raw Sequence Listing							
SEE OFFICE ACTION ON TH	E FOLLOWING PAGES						

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Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Claims 1-27 drawn to method and preparation, classified in class 536, subclass 23.1.
- II. Claims 28, drawn to a method of limiting damage to neuronal cells comprising administering a gene activation construct, classified in class 514, subclass 2.
- III. Claims 29-34, drawn to polypeptide, classified in class 530, subclass 350.
- IV. Claims 35-40, 42-48, drawn to nucleic acid, recombinant transfection system, probe, primer/kit, preparation thereof, classified in classes 536, 435, subclasses 232.1, 71.2, and 320.1.
- V. Claims 41, drawn to method of making a polypeptide, classified in class 435,
 subclass 70.1+.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve different methods employing different components for promoting the survival of different cells.

Inventions (I and II) and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product as the recited different product species.

Inventions III and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as the recited probes and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious

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variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions III and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as chemical means.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, because of their recognized divergent subject matter, and the search required for Group I is not required for Group II-V, restriction for examination purposes as indicated is proper.

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This application contains claims directed to the following patentably distinct species of the claimed invention:

1). Antisense (oligonucleotide), claims 13-15.

2). Protein Kinase A inhibitor:

a). 5-isoquinoline sulfonamide (claim 18)

B). The protein kinase inhibitor of Formula 19

c). Cyclic AMP

3). Nucleic acid of ID.7 or 8.

4). Polypeptide of ID.16 or 17.

Each of the above listed species of e.g., protein kinase inhibitor and antisense differs from one another in structure and possibly mode of action. Therefore, the groups have different issues regarding patentability and enablement and represent patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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This application fails to comply with the requirement of SEQUENCE RULE under 37 CFR 1.821 for the reasons set forth in the attachments.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703)308-3967. The examiner can normally be reached on Mon. to Fri. from 9 to 5:30.

tdw

September 22, 1998

PONNATHAPURA ACHUTAMURTHY PRIMARY EXAMINER **GROUP 1800**